

Serial No. 10/627,132
Amendment Dated June 10, 2005
Reply to Office Action of March 11, 2005

REMARKS

RESPONSE TO RESTRICTION REQUIREMENT MAILED MARCH 11, 2005

PROVISIONAL ELECTION

This response is being submitted in response to the Restriction Requirement contained within the office action mailed 03/11/2005, discussed by phone interview with Examiner Ibrahim on 02/28/05, in connection with the above-captioned application. The Applicants hereby provisionally elect "Invention I", Claims 1-12 drawn to an isolated nucleic acid, a vector, a host cell and transgenic plant/seed comprising said nucleic acid, and a plant transformation method. This election is made with traverse and without prejudice to Applicants' option to file divisional applications to the non-elected claims. The right to pursue examination of the non-elected claims in continuation or divisional applications is reserved. Reconsideration of the restrictions in this case is respectfully requested.

REMARKS RELATIVE TO RESTRICTION REQUIREMENT

The Examiner asserts that each isolated polynucleotide and each isolated polypeptide claimed in the application constitutes a distinct invention and that certain claims constitute independent inventions. The Applicants respectfully traverse.

The Examiner also asserts that Inventions I-III are distinct from each other, and states that "Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §806.05(f)). In the instant case, the isolated protein of Group II can be prepared by another and materially different process than that of

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Group I, such as chemical synthesis. In addition, the protein of Group II and the nucleic acid of Group I are patentably distinct inventions as they are directed to a divergent products having different structure, function and effects. Proteins are composed of amino acids, while nucleic acids are composed of purine and pyrimidine units; any relationship between nucleic acid and protein is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded protein. In the present claims, all the nucleic acid sequences of Group I do not necessarily encode all the proteins of Group II and all the proteins of Group II are not encoded by all the nucleic acids of Group I. For example, the nucleic acid of claim 1, part (g) comprises 25 contiguous bases of SEQ ID NO: 25, 27 or 29 which would not encode any of the polypeptides of Group II. Similarly, the nucleic acid of claim 1, parts (c) and (f) would not encode any of the polypeptides of Group II. The scope of the nucleic acid claims such as the DNA of claim 1 extends beyond the nucleic acids that encode the claimed polypeptides. A search of the nucleic acid of claim 1 would require an oligonucleotide search which is not likely to result in relevant art with respect to the proteins of Group II. For these reasons, the inventions of Groups I and II are patentably distinct, and searching them together would impose a serious search burden."

Further the Examiner states" The invention of Group I and III are unrelated because the instant specification does not show that the isolated nucleic acid of Group I can be used in the method of Group III. The instant specification does not disclose that the method of Group I and the method of Group III would be used together. The plant transformation method and the method for modifying gene expression are unrelated, as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs this function using structurally and functionally divergent

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material, and therefore the inventions I and III are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches."

Also, "the invention of Group II and III are unrelated because the instant specification does not show that the isolated protein of Group II can be used in the method of Group III. The inventions of Groups II and III have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups I and II together."

The Examiner concludes " Because these inventions are distinct for the reasons set forth above and have acquired a separate status in the art as shown by their different classifications and their recognized divergent subject matter and because the literature search required for Groups I and II is not coextensive, restriction for examination purposes as indicated is proper."

The Applicants respectfully traverse such assertions. These groups can clearly be used together.

Claim 13 (Invention II) is drawn to an isolated polypeptide related in the claimed manner to SEQ ID NO: 26, 28, or 30, encoded by the polynucleotide sequence of claim 1 (Invention I). In addition, claims 14-15 (Invention III) are directed to methods of modulating the level of cellulose synthase in a plant cell or a plant by modifying the expression in the transgenic plant of a polynucleotide of claim 1 (Invention I). Clearly the sequences, the recombinant expression cassette, host cell, plants and plant transformation of Invention I are capable of being used together with the protein of Invention II and the methods of Invention III.

Applicants respectfully assert that the Inventions I, II and III are related and have been disclosed as capable of use together. Further, the modes of operation, function, or effects have been shown to be related as evidenced above. The requirement of MPEP §§806.04 and 808.01 for independent, unrelated inventions have not been met and Claims 1-15 should not be held to be independent inventions.

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MPEP §808.01 states that inventions are independent "where they are not connected in design, operation, or effect under the disclosure of the particular application under consideration...." The disclosure of the present invention clearly connects the inventions of Inventions I, II and III. Invention I, II and III are connected by claims 9 and 11 which describe a method of modulating the level of cellulose synthase in a plant cell or a plant, respectively, through the introduction and modified expression of a polynucleotide of claim 1 (Invention I). Further, the specification on page 4, lines 9 -12 reads: "It is the object of the present invention to provide nucleic acids and proteins relating to cellulose synthases [Inventions I and II]. It is an object of the present invention to provide transgenic plants comprising the nucleic acids of the present invention [Invention I], and methods for modulating, in a transgenic plant, expression of the nucleic acids of the present invention [Invention III]"

In light of these remarks, the Applicants respectfully request that all of the claims (Inventions I, II and III) be considered a single invention. Applicants believe that the search and consideration of the cellulose synthase polynucleotides and the encoded polypeptides as claimed in the different composition and method claims of the present application is not burdensome to the Examiner. Applicants respectfully request that the current Restriction Requirement be reconsidered and withdrawn.

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Claims 1-12, and claimed SEQ ID NOS: 25-30 are all under consideration. Claims 1, 2, 8, 9 and 10 have been amended. Claims 13-15 have been withdrawn from consideration as they are drawn to a non-elected invention. No claims have been allowed.

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Claim Objections

Examiner has objected to claim 1 where the Examiner states, "member" should be changed to ---polynucleotide---, for clarification and consistency of claim language.

In an effort to particularly point out and more clearly define the subject matter claimed, the applicant has amended claim 1. The Applicant wishes to thank the Examiner for her suggested verbiage. It is believed that the claim as revised is free of the objections raised by the Examiner.

Claim Rejections under U.S.C. §112, second paragraph

Examiner has rejected claims 1-12 under 35 U.S.C §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claim 1 is rejected as indefinite for failing to recite the specific hybridization/wash conditions required for the claimed "stringent hybridization" conditions. Examiner states that the specification sets forth exemplary stringent conditions, but does not clearly define Applicant's "stringent conditions" and hence it is not known what is encompassed by the claim. Dependent claims 2-12 are included in the rejection.

In an effort to particularly point out and more clearly define the subject matter claimed the applicant has amended claim 1. It is believed that the claim as revised, and dependant claims 2-12 now particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant requests that the Examiners rejection of claims 1-12 under 35 U.S.C §112, second paragraph for indefiniteness be withdrawn.

Claim Rejections under U.S.C. §101 - Non-statutory subject matter

Claim 8 is rejected by the Examiner under 35 U.S.C. §101, because the claimed invention is directed to non-statutory subject matter. The claim does not

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recite "transgenic seed", and therefore the Examiner maintains that it reads on products of nature. Examiner further states that due to chimerism, not all cells of a transgenic plant contain the transgene, and therefore, a non-transgenic seed is not patentable. Examiner suggests that "transgenic" be inserted before "seed" in claim 8.

In an effort to particularly point out and more clearly define the subject matter claimed the applicant has amended claim 8. The Applicant wishes to thank the Examiner for her suggested verbiage. It is believed that the claim as revised no longer is directed to non-statutory matter. Applicant respectfully requests the Examiner to remove the rejection to claim 8 under 35 U.S.C. §101.

Claim Rejections under U.S.C. §112, first paragraph - Enablement

Claims 1-12 are rejected by the Examiner under 35 U.S.C. §112, first paragraph - Enablement. The Examiner characterizes the specification as enabling only for claims limited to the isolated polynucleotide comprising SEQ ID NO: 25, 27, or 29, polynucleotide sequences encoding SEQ ID NO: 26, 28, or 30, a recombinant expression, a plant/plant cell/ and seed comprising said polynucleotides, and a method of transforming a plant/plant cell with said expression cassette. The Examiner states that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims. Examiner asserts that the applicant has not taught the obtention and use of all the polynucleotides of claim 1 parts (a), (c), (d) and (g), nor does it demonstrate their ability to modulate the level of cellulose synthase in a transgenic plant. The Examiner states that further research not considered to be routine would be required before one skilled in the art would be able to know how to use the polynucleotides as claimed to modulate the level of cellulose synthase and achieve a desired agronomic trait in a transgenic plant. Examiner further asserts that since the working examples disclosed in the

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specification are limited to unmodified SEQ ID NO: 25, 27 and 29, the ability of said polynucleotides to encode a functional cellulose synthase and modulate level of cellulose synthase in transgenic plants cannot be extrapolated to a variant thereof, without specific guidance. Therefore, the Examiner concludes, that given the breadth of the claims, the lack of guidance, the unpredictability with regard to sequence modifications, and the limited working examples, the claimed invention is not enabled throughout the broad scope.

Applicant traverses.

As stated by the Federal Circuit, "patent applicants are not required to disclose every species encompassed by their claims...However, there must be sufficient disclosure through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention". *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 52 USPQ 2d 1129 (Fed. Cir. 1999) quoting *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ 2d 1438, 1445 & n.23 (Fed. Cir. 1991).

Additionally,

"a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed" *PPG Indus. V. Guardian Indus. Corp.*, 75 F.3d. 1558, 37 USPQ 2d 1618 (Fed. Cir. 1996) (quoting *Ex parte Jackson*, 217, USPQ 804, 807 (Bd. Pat. App. & Inter. 1982))

The claimed subject matter has been described in such a manner that allows others to make and use the invention. The specification provides detailed instruction for making and using the sequences disclosed, to transform plant cells, to alter the cellulose synthase concentration of said plant cells, thereby modifying the level of cellulose synthase in the plant.

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Applicant wishes to draw the examiner's attention to pages 24-25 in the specification as filed, where guidance regarding modified sequences is provided. One of skill in the art could predict which modifications would be tolerated by reference to a standard codon table. In addition, an example of guidance on the detection of polynucleotide expression is provided in the specification on pages 47-49. The specification provides sufficient guidance to allow one of skill in the art to recognize modified sequences that still express functional cellulose synthase. This information in the specification is further supported by the alignment of the cellulose synthase sequences contained in the originally submitted sequence listing. A multiple sequence alignment of said sequences is submitted with this document as Appendix 1. One of skill in the art would have no trouble aligning the sequences provided in the application, identifying the conserved regions, and making conservative sequence substitutions.

Additionally, in an effort to more distinctly point out the claimed subject matter, claims 1, 2, 8, 9 and 10 have been amended. Applicant submits that one of skill in the art would clearly know how to use the claimed invention. Applicant respectfully requests that the rejection of the claims under 35 U.S.C. §112, first paragraph for enablement, be withdrawn.

Claim rejections under U.S.C. §112, first paragraph – Written Description

Claims 1-12 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Examiner states that the claimed invention does not meet the current written description requirements for 3 reasons: the claims do not recite function, substantial variation in structures and function are expected among the claimed amplified polynucleotides and polynucleotides sharing only 25 contiguous bases, and the

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polynucleotides are only from a single plant species. Also, the Examiner states that the Applicant has not described which regions in the disclosed sequences will tolerate modifications, so that the desired polynucleotides can be obtained. Therefore, the Examiner concludes that the disclosed polynucleotide sequences are not a representative number of species of the polynucleotides of the genus claimed. The Examiner states that the specification fails to sufficiently describe the claimed invention in such full, clear, concise and exact terms that one skilled in the art would recognize that the Applicants are in possession of the invention as broadly claimed.

Applicant traverses. The specification discloses and describes multiple functional polynucleotides and polypeptides capable of altering the cellulose synthase composition in a plant. The sequence listing describes in detail the polynucleotides and polypeptides claimed as this invention. One of ordinary skill in the relevant art would have understood that the inventor, at the time the application was filed, had possession of the claimed invention.

As stated:

"Adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention....Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skills in the art that an appellant had possession of the concept of what is claimed."

In Staehelin v. Secher, 24 USPQ 2d 1513 (B.P. A.I. 1992)

When describing a representative number of species, it is not required that the description be of such specificity that it would provide individual support for each species that is encompassed by the genus. Additionally, one of skill in the art would understand that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed as described in Fed. Reg., Vol. 66, No. 4, 1099-1106 (2001).

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The specification discloses and describes multiple functional polynucleotides and polypeptides capable of altering the cellulose synthase composition in a plant. The sequence listing describes in detail the polynucleotides and polypeptides claimed as this invention. One of ordinary skill in the relevant art would have understood that the inventor, at the time the application was filed, had possession of the claimed invention.

However, in an effort to more clearly define the claimed invention, claims 1, 2, 8, 9 and 10 have been amended to more distinctly identify and clarify the subject matter that is being claimed. Applicant respectfully requests that the rejection of the claims under 35 U.S.C. §112, first paragraph for written description, be withdrawn.

Non-statutory Double Patenting Rejection

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of copending application No. 10/209,059. Examiner states that the conflicting claims are not identical, but are not patentably distinct from each other as each set of claims is directed to SEQ ID NOS: 25, 27 and 29. Examiner indicates that claims 1-12 cover similar subject matter, but are broader in scope than the copending claims of application No. 10/209,059, and therefore the claimed invention encompasses the invention claimed in the copending application.

In an effort to particularly point out and more clearly define the subject matter claimed the applicant has amended claims 1, 8, 9, and 10. It is believed that claims 1-12, as revised, now particularly point out and distinctly claim the subject matter which the applicant regards as the invention. SEQ ID NOS: 25-28 are no longer specified in the amended claims. Additionally, in the current application, SEQ ID NOS: 29 and 30 (3443 nucleotides and 1052 amino acids respectively) are not identical to the SEQ ID NOS: 29 and 30 of copending application No. 10/209,059 (3028 nucleotides and 927 amino acids respectively) and do not share at least 90%

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sequence identity as determined by the GAP algorithm under default parameters to the full length sequence. Therefore, the Applicant maintains that the claims as currently submitted no longer contain the common subject matter of copending application No. 10/209,059. Applicant requests that the Examiners provisional rejection of claims 1-12 for non-statutory double patenting be withdrawn.

Claim Rejections Under U.S.C. §102

Claims 1-12 are rejected under U.S.C. §102 (a) as being anticipated by Arioli et al (WO 98/00549). The Examiner asserts Arioli et al. teach isolated nucleic acid sequences from maize encoding a cellulose synthase, a recombinant expression construct comprising said nucleic acid sequence operably linked to a promoter, transgenic plants including monocot and dicot expressing said nucleic acid sequence, and a method for increasing the level of cellulose synthase in transgenic plants including maize and cotton by expressing the isolated nucleic acid sequence in sense or anti-sense orientation. The Examiner concludes that Arioli et al would inherently comprise the polynucleotide of claim 1(c) and (d). Therefore the Examiner concludes that Arioli et al teach all claim limitations.

The applicant traverses. Applicant submits that the disclosure by Arioli et al, does not teach all current claim elements, and does not anticipate the subject matter claimed as the invention.

As stated:

"[a]nticipation requires the disclosure in a single prior art reference of each element of the claim under consideration"

In W.L. Gore & Assoc. V. Garlock, Inc., 721 F.2d 1540. 220 USPQ 303, 313
(Fed. Cir. 1983)

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Additionally:

the prior art reference must disclose each element of the claimed invention
"arranged as in the claim."

In Lindermann Mashinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.
2d. 1452, 221 USPQ 481, 485 (Fed. Cir. 1984)

Applicant submits that the disclosure by Arioli et al., does not teach all claim limitations as submitted, and neither anticipates the subject matter of the invention. However, in an effort to more distinctly identify the subject matter claimed, the Applicant has amended claims 1, 2, 8, 9 and 10. The invention as currently claimed does not comprise the sequence disclosed by Arioli et al. Applicant respectfully requests that the rejection of the claims under 35 U.S.C. §102, be withdrawn.

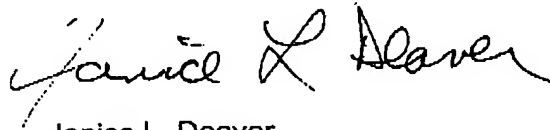
Conclusion

In view of the above amendments and remarks, Applicant submits that the rejections of claim 8 under 35 U.S.C. §101, and claims 1-12 under 35 U.S.C. §§112, and 102(a), as well as the non-statutory Double Patenting rejection have been overcome. Applicant respectfully submits that this application is now in condition for allowance and requests that a timely Notice of Allowance be issued in this case.

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If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

Respectfully submitted,
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